## REMARKS

Upon entry of the above amendment, claims 13-16, 38 and 42 will be in the case. Claims 37 and 39-41 have been cancelled by the above amendment.

The Examiner has rejected claims 13, 35, 36 and 42 under 35 U.S.C. 112, first paragraph. The Examiner states that "the term 'on demand' in claims 13, 35 and 36, and the phrase 'instructed to take a maintenance dose of the composition... to inhale additional doses' in claim 42 lack literal support."

While these phrases may lack literal, word-for-word support in the specification, it is axiomatic that the patent statute does not require such *ipsis verbis* support. See, e.g., Fujikawa v. Wattanasin, 39 USPQ2d 1895 (Fed. Cir. 1996). The Federal Circuit has confirmed that "the test for determining compliance with the written description requirement of §112 is whether the disclosure of the application as originally filed reasonably conveys to the artisan that the inventor had possession at that time of the later clamed subject matter, rather than the presence or absence of literal support in the specification for the claim language." In re Kaslow, 217 USPQ 1089 (Fed. Cir. 1983.)

In this case, the artisan would understand that the inventor had possession at the time filing of the claimed "on demand" administration, for example based on the teaching of "as needed use (Pro Re Nata, PRN)" at p. 4, lines 12-15 of Applicant's specification and in Example 6. The claim language of claim 42 finds support, for example, in Example 5, in which a patient is instructed to use the claimed combination for maintenance therapy, and then to take additional doses on an as needed basis.

Claims 13-15, 17, 18 and 20-42 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Carling et al.

Applicant maintains the position stated in Applicant's previous response, but will not reiterate the remarks made previously, for the sake of brevity. Instead, Applicants will respond to the Examiner's comments on Applicant's position.

First, the Examiner asserts that

> the Carling reference clearly teaches the suitable maximum daily dosage that can be inhaled in the treatment of asthma. By this one would motivate to instruct a patient to employ as needed up to maximum daily dosage that is taught by Carling. One would make such modification with reasonable expectation of success to treat asthma, safely and effectively since the as needed dosages for that subject is within the suitable daily dosage well taught by the Carling reference.

Applicant strenuously disagrees with the Examiner's conclusions in this regard. There is simply no recognition in the Carling reference that it would be desirable to instruct a patient to vary the daily dosage of the medication based on the patient's symptoms. Moreover, as explained in Applicant's previous response and declaration, instructing a patient to do so would have been counter to accepted medical practice at the time of Applicant's invention. Absent some suggestion in the cited art to instruct the patient as claimed, the Examiner's rejection is based solely on impermissible hindsight and unsupported speculation.

Second, the Examiner states that the declaration of Christer Hultquist, M.D., was not persuasive to the Examiner because

> the patients using the claimed "on demand" treatment protocol, for example in Appendix 6, only support the adjustable maintenance treatment representing "on demand" regimen as "bid" (twice a day) dosing which is encompassed by Carling's reference with Carling's suitable daily dosage. (under Methods, sentence begins with "After a 4-week...).

The Examiner is apparently confused regarding the experimental protocol described in Appendix 6. The sentence cited by the Examiner reads as follows:

> After a 4-week run-in period of fixed dosing (2 inhalations bid), 1034 patients were randomised to receive a further 6 months of either fixed dosing (2 inhalations bid) or adjustable dosing (step down to 1 inhalation bid as soon as asthma control is satisfactory, increase to 4 inhalations bid for 1-2 weeks in periods of asthma worsening.)

Thus, the group that received a fixed dosing of 2 inhalations bid was the *control* group. The adjustable dosing group was instructed to reduce their dosage and/or increase their dosage, based on their own evaluation of their individual symptoms. This is entirely consistent with Applicant's claimed invention, and entirely different from what is disclosed by Carling.

Thus, Applicant reiterates that the claims are patentable over Carling in view of the evidence and arguments submitted in Applicant's previous response.

Claims 16 and 19 have been rejected as unpatentable over Carling et al. in view of Aberg and Ryrfeldt. These secondary references do not supply what is lacking in Carling, and thus Applicant's submit that these claims are patentable for at least the reasons discussed above and in Applicant's previous response with regard to claim 13.

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